

K100327

MAR 22 2010



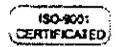
**HEARTWAY MEDICAL PRODUCTS CO.,LTD.**

NO.6, ROAD 25, TAICHUNG INDUSTRIAL PARK, TAICHUNG, TAIWAN R.O.C. 408

TEL.:886-4-23580357 (Sales)-23583232 (Rep) FAX:886-4-23590786

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**HEARTWAY**

**“ 510(k) SUMMARY ”**

Submitter's Name: **HEARTWAY Medical Products Co., Ltd.**

No.6, Road 25, Taichung Industrial Park, Taichung, 40850, Taiwan, ROC

Date summary prepared:

January 27, 2010

Device Name:

Proprietary Name: HEARTWAY Power Chair, P23  
 Common or Usual Name: POWERED WHEELCHAIR  
 Classification Name: POWERED WHEELCHAIR, Class II,  
 21 CFR 890.3860

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a seated position.

Description of the device:

The HEARTWAY Power Chair, P23 is an indoor / outdoor power chair that is battery operated. It has a base with four-wheeled with a seat, and armrests. The movement of the power chair is controlled by the rider who uses hand controls located at the top of the steering column. The device can be disassembled for transport and is provided with an onboard battery charger.

Performance Testing:

EMC Report ANSI / RESNA WC/Vol.2-1998, CISPR 11: 1990, EN61000-3-2: 1995, IEC61000-3-3:1995 (Electrically powered wheelchairs, scooters, and their chargers – requirements and test methods)

Legally marketed device for substantial equivalence comparison:

HEARTWAY Attendant-Controlled Power Chair, TC1 (K071006)



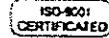
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### Summary for substantial equivalence comparison:

The intended use between the two devices is the same. Mainframes of two devices are folded, materials of the two devices all meet the strength and fatigue tests and they use the same material aspects. The same weight limit, cruising range, suspension of cross brace, size of rear wheels, footplates, armrest type, and the warranty are all the same. The back upholstery material is also the same fabric and passed the resistance ignition test. Especially the electronic systems between two devices are the same suppliers, and all passed by the UL certificated, for instance the electronic controller, batteries, and the competent switches and switching power supplies. Thus the same safety level for the two devices is assured.

The main different for the two devices are the feature of the predicate device is designed for attendant-controlled to drive, and the new device is designed for general used to drive. Thus, the differences between the two devices are very minor including overall dimension, wheelchair weight, size of front wheels and seat, incline capabilities, and the relevant specifications for ground clearance and curb climbing ability in the User's Manual. Thus for the real life use, the two devices are substantially equivalent.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Heartway Medical Products Co., Ltd.  
% Dr. Ke-Min Jin  
ROC Chinese – European Ind.  
No. 58, Fu-Chuin Street  
Hsin Chu City, TW HSQ  
China (Taiwan) 30067

MAR 22 2010

Re: K100327  
Trade/Device Name: HEARTWAY Power Chair, P23  
Regulation Number: 21 CFR 890.3860  
Regulation Name: Powered wheelchair  
Regulatory Class: II  
Product Code: ITI  
Dated: January 27, 2010  
Received: February 4, 2010

Dear Dr. Jin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

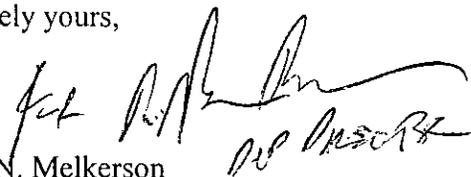
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

# Indications for Use

510 (K) Number ( If Known ):   K  

Device Name: HEARTWAY Power Chair, P23

Indications for Use:

The device is intended for medical purposes to provide mobility to persons restricted to a sitting position.

Prescription Use \_\_\_\_\_

AND/OR

Over-The-Counter Use   √  

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. MELKERSON

(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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